Liability Considerations in Clinical Trial
Agreements with Canadian Sites

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Clinical research rarely results in claims for subject injury or other causes of action, but when it does, pertinent laws, regulations, insurance protections, and contract terms become very important. This article addresses liability issues that sites, investigators, sponsors and contract research organizations (CROs) should consider when negotiating clinical trial agreements (CTAs) that involve Canadian sites. These issues involve liability coverage, governing law and jurisdiction, indemnification and physician status. This article applies to research conducted in the common law jurisdictions in Canada, meaning 12 of Canada’s 13 provinces and territories. Quebec, which is a civil law jurisdiction, is excluded from this discussion.

Liability Coverage

All parties to a CTA need to know what insurance or other liability coverage the research site, the investigator and other clinical trial personnel have.

In Canada, all provinces and territories maintain a universal healthcare system. If a subject is injured as a result of clinical research, he or she would likely be covered for reasonable and necessary expenses for medical care, including hospitalization, in the diagnosis and treatment of adverse reactions arising from clinical research. However, this system does have limits on its coverage, thus potentially exposing subjects to personal liability for any excess. Also, the system was not designed to assume liability for costs resulting from clinical research studies. As a result, Canadian sites and physicians sometimes depend on the subject injury coverage maintained by the pharmaceutical and medical device companies that conduct these studies.

In Canada, there is no private medical malpractice coverage for physicians. Rather, the Canadian Medical Protective Association (CMPA) covers Canadian physicians who are its members. This coverage extends to the performance of clinical trials. The CMPA is a non-profit organization funded and operated by physicians for physicians. There is no financial limit on its coverage. In addition, its coverage is occurrence-based, meaning that a physician is covered even if a claim is brought after a clinical trial is completed, provided he or she was a member of the CMPA during the clinical trial. The CMPA also generally covers any “research assistants” operating under the direct supervision or control of the physician and for whom that physician would be legally responsible. However, CMPA coverage generally excludes hospital or university employees or contractors who are involved with the clinical trial.

The CMPA’s coverage extends only to disputes based on the physician’s clinical professional work on the clinical trial. So, for example, if a physician or research assistant for whom he or she is legally responsible makes an error in prescribing or administering a drug in the course of the clinical trial or in conducting tests as part of the clinical trial, the CMPA would...
defend him or her in any legal proceedings and pay any damages that might be awarded to a clinical trial participant as a result of a court judgment or settlement. However, disputes related to issues like recruitment, availability of patients or facilities, financial matters, confidentiality, publication, intellectual property, and other commercial, administrative or non-medical matters are not generally covered by the CMPA.

The Canadian Nurses Protective Society (CNPS) covers nurses involved in clinical trials. It, too, is non-profit, and is owned and operated by nurses for nurses. Almost all of the various provincial and territorial associations and colleges are members of the CNPS. Nurses who are members of these associations and colleges are automatically entitled to CNPS protection and services. Like the CMPA, its coverage is occurrence-based. The coverage limits for each nurse are $1 million per incident and $3 million annual aggregate. The coverage limits for each nurse practitioner are $5 million per incident and $5 million annual aggregate. CNPS coverage extends to civil lawsuits, criminal charges, and alleged breach of statute (other than professional discipline or labor relations) arising from the provision of professional nursing services. For all such claims, the CNPS would defend the nurse or nurse practitioner in any legal proceedings and pay any damages that might be awarded as a result of a court judgment or settlement.

The College of Registered Nurses of British Columbia (CRNBC) is not a member of the CNPS, and therefore the CNPS does not automatically cover nurses who are only members of CRNBC. However, the CRNBC Captive Insurance Corporation (CIC) automatically provides liability coverage to nurses registered with CRNBC. CIC covers legal defense costs for negligence claims and pays damages awarded as a result of a court judgment or settlement. The coverage limits for each nurse are $1 million per incident and $1 million annual aggregate for negligence claims. The coverage limits for each nurse practitioner are $5 million per incident and $5 million annual aggregate for negligence claims. CIC also provides nurses and nurse practitioners with general liability coverage for claims involving property damage or bodily injury, with coverage limits of $2 million per incident and $2 million annual aggregate. CIC’s coverage for all claims is limited to claims that occur while a nurse is “practicing nursing.” In addition, it does not provide coverage to a nurse or nurse practitioner who “knowingly ignores” applicable legislation, policies or guidelines that pertain to nursing practice, or if someone suffers injury, sickness or disease caused by the nurse or nurse practitioner while he or she is committing a criminal act, violating any law, or under the influence of drugs.

Almost all universities in Canada are covered by the Canadian Universities Reciprocal Insurance Exchange (CURIE). CURIE is a reciprocal insurance exchange whose 58 member universities across Canada share losses arising from their operating risks. These risks include physical damage to assets, injuries or property damage of third parties, and liability for errors and omissions. This coverage varies by university but is commonly $5 million per incident and $5 million annual aggregate for each type of claim. CURIE also covers medical malpractice of any physician who is an employee of the university so long as the physician is also a member of the CMPA.

Hospital liability coverage in Canada varies. For example, the non-profit Healthcare Insurance Reciprocal of Canada (HIROC), the largest healthcare liability insurer in Canada, covers many healthcare facilities in Alberta, Manitoba, Newfoundland and Labrador, Ontario, Saskatchewan and the Yukon. Subscribers share losses. Coverage includes professional liability (medical malpractice), errors and omissions (directors and officers) liability, bodily injury, and property damage. As another example, Alberta Health Services provides liability coverage for almost all of Alberta’s major hospitals. Its coverage includes bodily injury, property damage, and errors and omissions. Hospital coverage in Canada varies by hospital, but is commonly $5 million per incident and $5 million annual aggregate for each of these
types of claims. Hospital liability coverage often excludes physicians, as they are usually contractors to, not employees of, a hospital.

Liability coverage for private clinics in Canada also varies. However, these clinics generally do not retain medical malpractice coverage. Rather, they rely on the CMPA, CNPS and CIC coverage discussed above. In addition, they usually maintain some form of commercial general liability insurance. However, this insurance does not cover medical malpractice or errors and omissions. As noted above, the CMPA also generally covers research assistants operating under the direct supervision or control of a CMPA-covered physician and for whom that physician would be legally responsible. This coverage may also extend to employees of the clinic, provided the employees do not have the ability to see and treat patients independently and further provided that various clinic ownership and other requirements are met.

**Governing Law and Jurisdiction**

The CMPA’s position on governing law is that it may not cover a physician involved in a clinical trial if the CTA is governed by the laws of a jurisdiction outside of Canada. Further, it may not cover a physician in an action relating to a clinical trial that is brought outside of Canada. The implications of ignoring these positions are that a physician may have to retain and pay for his or her own counsel and be held personally liable for any claims that result from a clinical trial. Therefore, a physician’s personal assets would be at risk. This is not an ideal situation for any of the parties involved. Obviously, the physician does not want to put his or her personal assets at risk. Nor do the sponsor or site want to look to a physician’s personal assets, rather than to a liability coverage provider. As a result, CTAs involving a Canadian site should stipulate to Canadian governing law and jurisdiction, at least for matters relating to CMPA liability coverage.

It is also not advisable for a CTA to “remain silent” on governing law and jurisdiction. Remaining silent allows a court, perhaps a court in a foreign jurisdiction, to stipulate the governing law and jurisdiction of the CTA. If the court stipulates a governing law or jurisdiction that is outside of Canada, the CMPA may refuse to cover the physician and his or her research assistants for that clinical trial.

CURIE and CIC also take the position that a claim must be filed in Canada for them to provide coverage, although their position on governing law is unclear.

**Indemnification**

Some sites in Canada are unable to indemnify for the acts of a third party, including physicians involved in clinical trials if they are independent contractors. For example, due to provincial legislation, almost every major hospital in Alberta is unable to indemnify for the acts of its physicians because they are independent contractors. In the event of a dispute, a court could decide to ignore any such indemnification in a CTA.

An alternative is to have the physician indemnify the sponsor. However, the CMPA generally does not consider itself bound by indemnities given by physicians to third parties. As a result, a physician personally would be liable for the indemnification. He or she would have to retain and pay for his or her own counsel and be held personally liable for any claims that result from the clinical trial. Therefore, a physician’s personal assets would be at risk. As noted above, this is not an ideal situation for any of the parties involved.

Another option is to have the site indemnify the sponsor but specifically exclude the acts of physicians. In this scenario, the physician should “assume responsibility” for his or her actions. Although CMPA may refuse to make any payment under a contractual

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indemnification, it will most likely respond if the physician is sued. By agreeing to “assume responsibility,” the physician is protecting his or her CMPA coverage, while also satisfying the sponsor by ensuring that he or she is assuming responsibility, i.e., liability, for his or her actions. Another option is to have the physician indemnify the sponsor, but only for claims to the extent covered by the CMPA. The CMPA has indicated that it may provide coverage to a physician where an indemnity made by that physician relates solely to the provision of medical services.

Physician Status
As mentioned earlier, at many sites, physicians are independent contractors, not employees. This relationship has important implications for CTAs. It means there would be no vicarious liability of the employer for the acts of an employee. An independent-contractor physician should thus be a party to the CTA. In other words, having the physician sign as having “read and acknowledged” the CTA will not suffice because he or she will avoid personal contract liability (but not tort liability that arises outside of the CTA). In such case, the site bears its, and the physician’s, entire contract liability responsibility. In addition, if the physician is an independent contractor, he or she should sign the CTA because the site may not have sufficient control over his or her actions to ensure that he or she complies with the CTA. Finally, as noted above, physicians often are not covered under the site’s insurance or indemnity. As a result, it is imperative that the physician be a member of the CMPA, so he or she has medical malpractice coverage.

Conclusion
Canada has a unique system of liability coverage, which offers significant advantages to all parties, provided the rules are followed and certain precautions taken. Parties entering into a CTA should be aware of the specific coverages available to the site, investigator and other research personnel.

Sources

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